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PFIZER INC.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE CELEBREX AND BEXTRA
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

This document relates to

MARY SHAW,

Plaintiff,

vs.

PFIZER, INC.,

Defendant.

) MDL Docket No. 1699

) CASE NO. 3:07-cv-5951-CRB

) **PFIZER INC.'S ANSWER TO
COMPLAINT**

) **JURY DEMAND ENDORSED
HEREIN**

1 NOW COMES Defendant Pfizer Inc. (improperly captioned in Plaintiff's Complaint as
2 "Pfizer, Inc.") ("Pfizer" or "Defendant") and files this Answer to Plaintiff's Complaint
3 ("Complaint"), and would respectfully show the Court as follows:

4 **I.**

5 **ANSWER**

6 1. Defendant admits that Plaintiff brought this civil action seeking monetary damages, but
7 denies that Plaintiff is entitled to any relief or damages. Defendant is without knowledge or
8 information sufficient to form a belief as to the truth of the allegations in this paragraph of the
9 Complaint regarding Plaintiff's medical condition and whether Plaintiff used Bextra®, and,
10 therefore, denies the same. Defendant states that Bextra® was and is safe and effective when
11 used in accordance with its FDA-approved prescribing information. Defendant denies any
12 wrongful conduct, denies that Bextra® caused Plaintiff injury or damage, and denies the
13 remaining allegations in this paragraph of the Complaint.

14 **Response to Allegations Regarding Parties**

15 2. Defendant is without knowledge or information sufficient to form a belief as to the truth
16 of the allegations regarding Plaintiff's citizenship and residency, and, therefore, denies the
17 same. Defendant denies that Bextra® caused Plaintiff injury or damage and denies the
18 remaining allegations in this paragraph of the Complaint.

19 3. Defendant admits that Pfizer is a Delaware corporation with its principal place of
20 business in New York. Defendant admits that Pfizer is registered to do and does business in
21 South Carolina. Defendant admits that Pfizer may be served through its registered agent.
22 Defendant denies any wrongful conduct, denies that Pfizer committed a tort in the South
23 Carolina, New York, or California, and denies the remaining allegations in this paragraph of the
24 Complaint.

25 4. Defendant admits that Pharmacia acquired Searle in 2000 and that, as the result of a
26 merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendant denies
27 any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

28 5. Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted

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Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant admits that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant admits that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle became a subsidiary of Pfizer. Defendant denies the remaining allegations in this paragraph of the Complaint.

6. Defendant admits that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendant denies the remaining allegations in this paragraph of the Complaint.

7. Defendant admits that Pharmacia acquired Searle in 2000. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

8. Defendant admits that, as the result of a merger in April 2003, Pharmacia became a subsidiary of Pfizer. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

Response to Allegations Regarding Jurisdiction and Venue

9. Defendant is without knowledge or information to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's citizenship and the amount in controversy, and, therefore, denies that the same. However, Defendant admits that Plaintiff claims that the parties are diverse and that the amount in controversy exceeds \$75,000, exclusive of interests and costs.

10. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding the judicial district in which the asserted claims allegedly arose, and, therefore, denies the same. Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted Bextra® in the United States, including California, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant states that Bextra®

1 was and is safe and effective when used in accordance with its FDA-approved prescribing
2 information. Defendant states that the potential effects of Bextra® were and are adequately
3 described in its FDA-approved prescribing information, which was at all times adequate and
4 comported with applicable standards of care and law. Defendant denies any wrongful conduct,
5 denies committing a tort in the States of California, New York, or South Carolina, and denies
6 the remaining allegations in this paragraph of the Complaint.

7 **Response to Factual Allegations**

8 11. Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted
9 Bextra® in the United States, including South Carolina and New York, to be prescribed by
10 healthcare providers who are by law authorized to prescribe drugs in accordance with their
11 approval by the FDA. Defendant admits that Pfizer provided FDA-approved prescribing
12 information regarding Bextra®. Defendant denies the remaining allegations in this paragraph
13 of the Complaint.

14 12. Defendant is without knowledge or information sufficient to form a belief as to the truth
15 of the allegations in this paragraph of the Complaint regarding Plaintiff's medical condition and
16 whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant denies the
17 remaining allegations in this paragraph of the Complaint.

18 13. Defendant is without knowledge or information sufficient to form a belief as to the truth
19 of the allegations in this paragraph of the Complaint regarding Plaintiff's medical condition and
20 whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra®
21 was and is safe and effective when used in accordance with its FDA-approved prescribing
22 information. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff
23 injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

24 14. Defendant is without knowledge or information sufficient to form a belief as to the truth
25 of the allegations in this paragraph of the Complaint regarding Plaintiff's medical condition,
26 therefore, denies the same. Defendant denies any wrongful conduct, denies that Bextra®
27 caused Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the
28 Complaint.

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1 15. Defendant is without knowledge or information sufficient to form a belief as to the truth
2 of the allegations in this paragraph of the Complaint regarding Plaintiff's medical condition,
3 therefore, denies the same. Defendant denies any wrongful conduct, denies that Bextra®
4 caused Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the
5 Complaint.

6 16. Defendant states that Bextra® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendant states that the potential effects of
8 Bextra® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
11 of the Complaint.

12 17. Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted
13 Bextra® in the United States to be prescribed by healthcare providers who are by law
14 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant admits
15 that Pfizer provided FDA-approved prescribing information regarding Bextra®. Defendant
16 denies the remaining allegations in this paragraph of the Complaint.

17 18. Defendant admits that Bextra® is in a class of drugs that is, at times, referred to as non-
18 steroidal anti-inflammatory drugs ("NSAIDs"). Defendant states that, as stated in the FDA-
19 approved labeling for Bextra®, "[t]he mechanism of action is believed to be due to the
20 inhibition of prostaglandin synthesis primarily through inhibition of cyclooxygenase-2 (COX-
21 2). Defendant denies the remaining allegations in this paragraph of the Complaint.

22 19. Defendant admits that Bextra® was approved by the FDA on November 16, 2001.
23 Defendant admits, as indicated in the package insert approved by the FDA, that Bextra® is
24 indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid
25 arthritis, as well as for the treatment of primary dysmenorrhea. Defendant denies the remaining
26 allegations in this paragraph of the Complaint.

27 20. Defendant admits that the sale of Bextra® was voluntarily suspended in the U.S. market
28 as of April 7, 2005. Defendant states that Bextra® was and is safe and effective when used in

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1 accordance with its FDA-approved prescribing information. Defendant states that the potential
2 effects of Bextra® were and are adequately described in its FDA-approved prescribing
3 information, which was at all times adequate and comported with applicable standards of care
4 and law. Defendant denies any wrongful conduct and denies the remaining allegations in this
5 paragraph of the Complaint.

6 21. Defendant states that the referenced article speaks for itself and respectfully refers the
7 Court to the article for its actual language and text. Any attempt to characterize the article is
8 denied. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
9 damage, and denies the remaining allegations in this paragraph of the Complaint.

10 22. Defendant states that the referenced article speaks for itself and respectfully refers the
11 Court to the article for its actual language and text. Any attempt to characterize the article is
12 denied. Defendant denies the remaining allegations in this paragraph of the Complaint.

13 23. Defendant states that Bextra® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendant denies any wrongful conduct,
15 denies that Bextra® caused Plaintiff injury or damage, and denies the remaining allegations in
16 this paragraph of the Complaint.

17 24. Defendant is without knowledge or information sufficient to form a belief as to the truth
18 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
19 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
20 when used in accordance with its FDA-approved prescribing information. Defendant states that
21 the potential effects of Bextra® were and are adequately described in its FDA-approved
22 prescribing information, which was at all times adequate and comported with applicable
23 standards of care and law. Defendant denies any wrongful conduct and denies the remaining
24 allegations in this paragraph of the Complaint.

25 25. Defendant states that Bextra® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendant states that the potential effects of
27 Bextra® were and are adequately described in its FDA-approved prescribing information,
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendant admits that Pfizer provided FDA-approved prescribing information regarding
2 Bextra®. Defendant denies any wrongful conduct and denies the remaining allegations in this
3 paragraph of the Complaint.

4 26. Defendant states that Bextra® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendant states that the potential effects of
6 Bextra® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
9 of the Complaint.

10 27. Defendant is without knowledge or information sufficient to form a belief as to the truth
11 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
12 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
13 when used in accordance with its FDA-approved prescribing information. Defendant states that
14 the potential effects of Bextra® were and are adequately described in its FDA-approved
15 prescribing information, which was at all times adequate and comported with applicable
16 standards of care and law. Defendant denies any wrongful conduct and denies the remaining
17 allegations in this paragraph of the Complaint.

18 28. Defendant is without knowledge or information sufficient to form a belief as to the truth
19 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
20 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
21 when used in accordance with its FDA-approved prescribing information. Defendant states that
22 the potential effects of Bextra® were and are adequately described in its FDA-approved
23 prescribing information, which was at all times adequate and comported with applicable
24 standards of care and law. Defendant denies any wrongful conduct and denies the remaining
25 allegations in this paragraph of the Complaint.

26 29. Defendant is without knowledge or information sufficient to form a belief as to the truth
27 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
28 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective

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1 when used in accordance with its FDA-approved prescribing information. Defendant states that
2 the potential effects of Bextra® were and are adequately described in its FDA-approved
3 prescribing information, which was at all times adequate and comported with applicable
4 standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® caused
5 Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the
6 Complaint.

7 30. Defendant is without knowledge or information sufficient to form a belief as to the truth
8 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
9 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
10 when used in accordance with its FDA-approved prescribing information. Defendant states that
11 the potential effects of Bextra® were and are adequately described in its FDA-approved
12 prescribing information, which was at all times adequate and comported with applicable
13 standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® caused
14 Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the
15 Complaint.

16 31. Defendant is without knowledge or information sufficient to form a belief as to the truth
17 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
18 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
19 when used in accordance with its FDA-approved prescribing information. Defendant states that
20 the potential effects of Bextra® were and are adequately described in its FDA-approved
21 prescribing information, which was at all times adequate and comported with applicable
22 standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® caused
23 Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the
24 Complaint.

25 32. Defendant denies any wrongful conduct and denies the remaining allegations in this
26 paragraph of the Complaint.

27 **Response to Allegations Regarding Fraudulent Concealment**

28 33. Defendant states that Bextra® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendant states that the potential effects of
2 Bextra® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
5 of the Complaint.

6 34. Defendant states that Bextra® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendant states that the potential effects of
8 Bextra® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
11 of the Complaint.

12 35. Defendant states that Bextra® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendant states that the potential effects of
14 Bextra® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
17 of the Complaint.

18 36. Defendant states that this paragraph of the Complaint contains legal contentions to
19 which no response is deemed required. To the extent a response is deemed required, Defendant
20 states that Bextra® was and is safe and effective when used in accordance with its FDA-
21 approved prescribing information. Defendant states that the potential effects of Bextra® were
22 and are adequately described in its FDA-approved prescribing information, which was at all
23 times adequate and comported with applicable standards of care and law. Defendant denies any
24 wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

25 **Response to First Cause of Action: Strict Products Liability –Design Defect**

26 37. Defendant incorporates by reference their responses to each paragraph of Plaintiff's
27 Complaint as if fully set forth herein.

28 38. Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted

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1 Bextra® in the United States to be prescribed by healthcare providers who are by law
2 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies
3 the remaining allegations in this paragraph of the Complaint.

4 39. Defendant states that Bextra® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendant states that the potential effects of
6 Bextra® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendant denies any wrongful conduct, denies that Bextra® is defective or unreasonably
9 dangerous, and denies the remaining allegations in this paragraph of the Complaint.

10 40. Defendant is without knowledge or information sufficient to form a belief as to the truth
11 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
12 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
13 when used in accordance with its FDA-approved prescribing information. Defendant states that
14 the potential effects of Bextra® were and are adequately described in its FDA-approved
15 prescribing information, which was at all times adequate and comported with applicable
16 standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is
17 defective, and denies the remaining allegations in this paragraph of the Complaint.

18 41. Defendant states that Bextra® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendant states that the potential effects of
20 Bextra® were and are adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the
23 remaining allegations in this paragraph of the Complaint.

24 42. Defendant is without knowledge or information sufficient to form a belief as to the truth
25 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
26 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
27 when used in accordance with its FDA-approved prescribing information. Defendant states that
28 the potential effects of Bextra® were and are adequately described in its FDA-approved

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1 prescribing information, which was at all times adequate and comported with applicable
2 standards of care and law. Defendant denies any wrongful conduct and denies the remaining
3 allegations in this paragraph of the Complaint.

4 43. Defendant is without knowledge or information sufficient to form a belief as to the truth
5 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
6 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
7 when used in accordance with its FDA-approved prescribing information. Defendant states that
8 the potential effects of Bextra® were and are adequately described in its FDA-approved
9 prescribing information, which was at all times adequate and comported with applicable
10 standards of care and law. Defendant denies any wrongful conduct and denies the remaining
11 allegations in this paragraph of the Complaint.

12 44. Defendant is without knowledge or information sufficient to form a belief as to the truth
13 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
14 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
15 when used in accordance with its FDA-approved prescribing information. Defendant states that
16 the potential effects of Bextra® were and are adequately described in its FDA-approved
17 prescribing information, which was at all times adequate and comported with applicable
18 standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® caused
19 Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the
20 Complaint.

21 45. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
22 damage, and denies the remaining allegations in this paragraph of the Complaint.

23 **Response to Second Cause of Action: Strict Product Liability – Warning Defect**

24 46. Defendant incorporates by reference their responses to each paragraph of Plaintiff's
25 Complaint as if fully set forth herein.

26 47. Defendant states that Bextra® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendant states that the potential effects of
28 Bextra® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the
3 remaining allegations in this paragraph of the Complaint.

4 48. Defendant states that Bextra® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendant states that the potential effects of
6 Bextra® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the
9 remaining allegations in this paragraph of the Complaint.

10 49. Defendant is without knowledge or information sufficient to form a belief as to the truth
11 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
12 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
13 when used in accordance with its FDA-approved prescribing information. Defendant states that
14 the potential effects of Bextra® were and are adequately described in its FDA-approved
15 prescribing information, which was at all times adequate and comported with applicable
16 standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® caused
17 Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the
18 Complaint.

19 50. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
20 damage, and denies the remaining allegations in this paragraph of the Complaint.

21 **Response to Third Cause of Action: Strict Product Liability – Testing Defect**

22 51. Defendant incorporates by reference their responses to each paragraph of Plaintiff's
23 Complaint as if fully set forth herein.

24 52. Defendant states that Bextra® was and is safe and effective when used in accordance
25 with its FDA-approved prescribing information. Defendant states that the potential effects of
26 Bextra® were and are adequately described in its FDA-approved prescribing information,
27 which was at all times adequate and comported with applicable standards of care and law.
28 Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the

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1 remaining allegations in this paragraph of the Complaint.

2 53. Defendant states that Bextra® was and is safe and effective when used in accordance
3 with its FDA-approved prescribing information. Defendant states that the potential effects of
4 Bextra® were and are adequately described in its FDA-approved prescribing information,
5 which was at all times adequate and comported with applicable standards of care and law.
6 Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the
7 remaining allegations in this paragraph of the Complaint.

8 54. Defendant states that Bextra® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendant states that the potential effects of
10 Bextra® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the
13 remaining allegations in this paragraph of the Complaint. Defendant denies any wrongful
14 conduct, denies that Bextra® is defective, denies that Bextra® caused Plaintiff injury or
15 damage, and denies the remaining allegations in this paragraph of the Complaint.

16 55. Defendant is without knowledge or information sufficient to form a belief as to the truth
17 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
18 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
19 when used in accordance with its FDA-approved prescribing information. Defendant states that
20 the potential effects of Bextra® were and are adequately described in its FDA-approved
21 prescribing information, which was at all times adequate and comported with applicable
22 standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® caused
23 Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the
24 Complaint.

25 **Response to Fourth Cause of Action: Fraud**

26 56. Defendant incorporates by reference their responses to each paragraph of Plaintiff's
27 Complaint as if fully set forth herein.

28 57. Defendant states that Bextra® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendant states that the potential effects of
2 Bextra® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
5 of the Complaint.

6 58. Defendant is without knowledge or information sufficient to form a belief as to the truth
7 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
8 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
9 when used in accordance with its FDA-approved prescribing information. Defendant states that
10 the potential effects of Bextra® were and are adequately described in its FDA-approved
11 prescribing information, which was at all times adequate and comported with applicable
12 standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® caused
13 Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the
14 Complaint.

15 59. Defendant is without knowledge or information sufficient to form a belief as to the truth
16 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
17 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
18 when used in accordance with its FDA-approved prescribing information. Defendant states that
19 the potential effects of Bextra® were and are adequately described in its FDA-approved
20 prescribing information, which was at all times adequate and comported with applicable
21 standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® caused
22 Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the
23 Complaint.

24 **Response to Fifth Cause of Action: Negligence**

25 60. Defendant incorporates by reference their responses to each paragraph of Plaintiff's
26 Complaint as if fully set forth herein.

27 61. Defendant states that this paragraph of the Complaint contains legal contentions to
28 which no response is deemed required. To the extent a response is deemed required, Defendant

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1 admits that Pfizer had duties as are imposed by law but denies having breached such duties.
2 Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted
3 Bextra® in the United States to be prescribed by healthcare providers who are by law
4 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies
5 the remaining allegations in this paragraph of the Complaint.

6 62. Defendant states that Bextra® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendant states that the potential effects of
8 Bextra® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
11 of the Complaint.

12 63. Defendant states that Bextra® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendant states that the potential effects of
14 Bextra® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendant denies any wrongful conduct, denies that Bextra® is unreasonably dangerous, and
17 denies the remaining allegations in this paragraph of the Complaint.

18 64. Defendant states that this paragraph of the Complaint contains legal contentions to
19 which no response is deemed required. To the extent a response is deemed required, Defendant
20 admits that Pfizer had duties as are imposed by law but denies having breached such duties.
21 Defendant is without knowledge or information sufficient to form a belief as to the truth of the
22 allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and,
23 therefore, denies the same. Defendant states that Bextra® was and is safe and effective when
24 used in accordance with its FDA-approved prescribing information. Defendant states that the
25 potential effects of Bextra® were and are adequately described in its FDA-approved prescribing
26 information, which was at all times adequate and comported with applicable standards of care
27 and law. Defendant denies any wrongful conduct and denies the remaining allegations in this
28 paragraph of the Complaint.

65. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

Response to Sixth Cause of Action: Negligent Misrepresentation

66. Defendant incorporates by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

67. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

68. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra® caused Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the Complaint, including all subparts.

Response to Seventh Cause of Action: Express Warranty for Goods

69. Defendant incorporates by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

70. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is deemed required. To the extent a response is deemed required, Defendant admits that Pfizer had duties as are imposed by law but denies having breached such duties. Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law

1 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant states
2 that Bextra® was and is safe and effective when used in accordance with its FDA-approved
3 prescribing information. Defendant states that the potential effects of Bextra® were and are
4 adequately described in its FDA-approved prescribing information, which was at all times
5 adequate and comported with applicable standards of care and law. Defendant denies any
6 wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

7 71. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
8 damage, and denies the remaining allegations in this paragraph of the Complaint.

9 **Response to Eighth Cause of Action: Implied Warranty of Merchantability**

10 72. Defendant incorporates by reference their responses to each paragraph of Plaintiff's
11 Complaint as if fully set forth herein.

12 73. Defendant is without knowledge or information sufficient to form a belief as to the truth
13 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
14 and, therefore, denies the same. Defendant admits that, during certain periods of time, Pfizer
15 marketed and co-promoted Bextra® in the United States to be prescribed by healthcare
16 providers who are by law authorized to prescribe drugs in accordance with their approval by the
17 FDA. Defendant states that Bextra® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendant states that the potential effects of
19 Bextra® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
22 of the Complaint.

23 74. Defendant states that Bextra® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendant states that the potential effects of
25 Bextra® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra®
28 caused Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the

1 Complaint.

2 **Response to Ninth Cause of Action: Implied Warranty of Fitness**

3 75. Defendant incorporates by reference their responses to each paragraph of Plaintiff's
4 Complaint as if fully set forth herein.

5 76. Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted
6 Bextra® in the United States to be prescribed by healthcare providers who are by law
7 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant admits,
8 as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the
9 relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for
10 the treatment of primary dysmenorrhea. Defendant states that Bextra® was and is safe and
11 effective when used in accordance with its FDA-approved prescribing information. Defendant
12 states that the potential effects of Bextra® were and are adequately described in its FDA-
13 approved prescribing information, which was at all times adequate and comported with
14 applicable standards of care and law. Defendant denies any wrongful conduct and denies the
15 remaining allegations in this paragraph of the Complaint.

16 77. Defendant is without knowledge or information sufficient to form a belief as to the truth
17 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
18 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
19 when used in accordance with its FDA-approved prescribing information. Defendant states that
20 the potential effects of Bextra® were and are adequately described in its FDA-approved
21 prescribing information, which was at all times adequate and comported with applicable
22 standards of care and law. Defendant denies the remaining allegations in this paragraph of the
23 Complaint.

24 78. Defendant states that Bextra® was and is safe and effective when used in accordance
25 with its FDA-approved prescribing information. Defendant states that the potential effects of
26 Bextra® were and are adequately described in its FDA-approved prescribing information,
27 which was at all times adequate and comported with applicable standards of care and law.
28 Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or damage,

1 and denies the remaining allegations in this paragraph of the Complaint.

2 **Response to Tenth Cause of Action: Deceptive Business Practices**

3 79. Defendant is without knowledge or information sufficient to form a belief as to the truth
4 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
5 and, therefore, denies the same. Defendant admits that, during certain periods of time, Pfizer
6 marketed and co-promoted Bextra® in the United States to be prescribed by healthcare
7 providers who are by law authorized to prescribe drugs in accordance with their approval by the
8 FDA. Defendant admits that Pfizer provided FDA-approved prescribing information regarding
9 Bextra®. Defendant denies the remaining allegations in this paragraph of the Complaint.

10 80. Defendant states that Bextra® was and is safe and effective when used in accordance
11 with its FDA-approved prescribing information. Defendant states that the potential effects of
12 Bextra® were and are adequately described in its FDA-approved prescribing information,
13 which was at all times adequate and comported with applicable standards of care and law.
14 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
15 of the Complaint.

16 81. Defendant is without knowledge or information sufficient to form a belief as to the truth
17 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
18 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
19 when used in accordance with its FDA-approved prescribing information. Defendant states that
20 the potential effects of Bextra® were and are adequately described in its FDA-approved
21 prescribing information, which was at all times adequate and comported with applicable
22 standards of care and law. Defendant denies any wrongful conduct and denies the remaining
23 allegations in this paragraph of the Complaint.

24 82. Defendant is without knowledge or information sufficient to form a belief as to the truth
25 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
26 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
27 when used in accordance with its FDA-approved prescribing information. Defendant states that
28 the potential effects of Bextra® were and are adequately described in its FDA-approved

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1 prescribing information, which was at all times adequate and comported with applicable
2 standards of care and law. Defendant denies any wrongful conduct and denies the remaining
3 allegations in this paragraph of the Complaint.

4 83. Defendant is without knowledge or information sufficient to form a belief as to the truth
5 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
6 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
7 when used in accordance with its FDA-approved prescribing information. Defendant states that
8 the potential effects of Bextra® were and are adequately described in its FDA-approved
9 prescribing information, which was at all times adequate and comported with applicable
10 standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® caused
11 Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the
12 Complaint.

13 84. Defendant states that Bextra® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendant states that the potential effects of
15 Bextra® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
18 of the Complaint.

19 85. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
20 damage, and denies the remaining allegations in this paragraph of the Complaint.

21 **Response to Allegation Regarding Punitive Damages**

22 86. Defendant states that Bextra® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendant states that the potential effects of
24 Bextra® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra®
27 caused Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the
28 Complaint.

Response to Jury Demand

87. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required.

Response to Prayer for Relief

Answering the unnumbered paragraph of the Complaint entitled “Prayer for Relief,” Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or damage, and denies the remaining allegations in this paragraph of the Complaint, including all subparts.

II.

GENERAL DENIAL

Defendant denies all allegations and/or legal conclusions set forth in Plaintiff’s Complaint that have not been previously admitted, denied, or explained.

III.

AFFIRMATIVE DEFENSES

Defendant reserves the right to rely upon any of the following or additional defenses to claims asserted by Plaintiff to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendant affirmatively shows that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Bextra® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendant’s labeling and warning of Bextra® was at all times in compliance with applicable federal law. Plaintiff’s causes of action against Defendant, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendant provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at

the time.

Fourth Defense

4. At all relevant times, Defendant's warnings and instructions with respect to the use of Bextra® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendant.

Sixth Defense

6. Plaintiff's action is barred by the statute of repose.

Seventh Defense

7. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the negligence or fault of the Plaintiff and Plaintiff's damages, if any, are barred or reduced by the doctrines of comparative fault and contributory negligence and by the failure to mitigate damages.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or omissions on the part of Defendant. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendant and for whose acts or omissions Defendant is not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendant cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiff were not caused by Bextra®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendant affirmatively denies that they violated any duty owed to Plaintiff.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a “learned intermediary” in determining the use of the product. Bextra® is a prescription medical product, available only on the order of a licensed physician. Bextra® provided an adequate warning to Plaintiff’s treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Bextra® at the time of the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiff’s causes of action are barred in whole or in part by the lack of a defect as the Bextra® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the unforeseeable alteration, change, improper handling, abnormal use, or other unforeseeable misuse of Bextra® by persons other than Defendant or persons acting on its behalf after the product left the control of Defendant.

Seventeenth Defense

17. Plaintiff’s alleged damages were not caused by any failure to warn on the part of

Defendant.

Eighteenth Defense

18. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Bextra®.

Nineteenth Defense

19. Plaintiff knew or should have known of any risk associated with Bextra®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiff is barred from recovering against Defendant because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-first Defense

21. Plaintiff's claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

Twenty-third Defense

23. Plaintiff's claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiff's claims are barred in whole or in part because Defendant provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. The imposition of punitive damages in this case would violate Defendant's rights to procedural due process under the Fourteenth Amendment of the United States Constitution and the Constitutions of the States of California, New York, and South Carolina, and would additionally violate Defendant's right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiff's punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendant's nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendant.

Thirty-fifth Defense

35. Plaintiff failed to provide Defendant with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendant's rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution and the Constitutions of the States of California, New York and South Carolina. Any law, statute, or

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other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendant; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Bextra®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Bextra® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

1 **Forty-first Defense**

2 41. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information
3 and belief, such injuries and losses were caused by the actions of persons not having real or
4 apparent authority to take said actions on behalf of Defendant and over whom Defendant had
5 no control and for whom Defendant may not be held accountable.

6 **Forty-second Defense**

7 42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra®
8 was not unreasonably dangerous or defective, was suitable for the purpose for which it was
9 intended, and was distributed with adequate and sufficient warnings.

10 **Forty-third Defense**

11 43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches,
12 waiver, and/or estoppel.

13 **Forty-fourth Defense**

14 44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the
15 pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or
16 illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were
17 independent of or far removed from Defendant's conduct.

18 **Forty-fifth Defense**

19 45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra®
20 did not proximately cause injuries or damages to Plaintiff.

21 **Forty-sixth Defense**

22 46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff
23 did not incur any ascertainable loss as a result of Defendant's conduct.

24 **Forty-seventh Defense**

25 47. The claims asserted in the Complaint are barred, in whole or in part, because the
26 manufacturing, labeling, packaging, and any advertising of the product complied with the
27 applicable codes, standards and regulations established, adopted, promulgated or approved by
28

1 any applicable regulatory body, including but not limited to the United States, any state, and
2 any agency thereof.

3 **Forty-eighth Defense**

4 48. The claims must be dismissed because Plaintiff would have taken Bextra® even if the
5 product labeling contained the information that Plaintiff contends should have been provided.

6 **Forty-ninth Defense**

7 49. The claims asserted in the Complaint are barred because the utility of Bextra®
8 outweighed its risks.

9 **Fiftieth Defense**

10 50. Plaintiff's damages, if any, are barred or limited by the payments received from
11 collateral sources.

12 **Fifty-first Defense**

13 51. Defendant's liability, if any, can only be determined after the percentages of
14 responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if
15 any, are determined. Defendant seeks an adjudication of the percentage of fault of the
16 claimants and each and every other person whose fault could have contributed to the alleged
17 injuries and damages, if any, of Plaintiff.

18 **Fifty-second Defense**

19 52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the
20 common law gives deference to discretionary actions by the United States Food and Drug
21 Administration under the Federal Food, Drug, and Cosmetic Act.

22 **Fifty-third Defense**

23 53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is
24 comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act
25 ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff's
26 claims conflict with the FDCA, with the regulations promulgated by FDA to implement the
27 FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations,
28 and with the specific determinations by FDA specifying the language that should be used in the

1 labeling accompanying Bextra®. Accordingly, Plaintiff's claims are preempted by the
2 Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the
3 United States.

4 **Fifty-fourth Defense**

5 54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity
6 required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

7 **Fifty-fifth Defense**

8 55. Defendant states on information and belief that the Complaint and each purported cause
9 of action contained therein is barred by the statutes of limitations contained in California Code
10 of Civil Procedure §§ 335.1 and 338 and former § 340(3), such other statutes of limitation as
11 may apply.

12 **Fifty-sixth Defense**

13 56. Defendant states on information and belief that any injuries, losses, or damages suffered
14 by Plaintiff were proximately caused, in whole or in part, by the negligence or other actionable
15 conduct of persons or entities other than Defendant. Therefore, Plaintiff's recovery against
16 Defendant, if any, should be reduced pursuant to California Civil Code § 1431.2.

17 **Fifty-seventh Defense**

18 57. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of
19 Defendant, no act or omission was oppressive, fraudulent, or malicious under California Civil
20 Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive
21 damages is also barred under California Civil Code § 3294(b).

22 **Fifty-eighth Defense**

23 58. In the event Plaintiff recovers a verdict or judgment against Defendant, then said verdict
24 or judgment must be reduced pursuant to CPLR 4545(c), and/or other applicable State or
25 Commonwealth statutes, by those amounts which have, or will, with reasonable certainty,
26 replace or indemnify Plaintiff, in whole or in part, for any past or future claimed medical
27 expenses or other such economic loss, paid from any collateral source such as insurance, social
28 security, workers' compensation or employee benefit programs.

Fifty-ninth Defense

59. In accordance with CPLR 1601 et seq., and/or other applicable State or Commonwealth statutes, the liability of Defendant, if any, to Plaintiff contends for non-economic loss is limited to its equitable share, determined in accordance with the relative culpability of all persons or entities contributing to the total liability for non-economic loss, including named parties and others over whom Plaintiff contends could have obtained personal jurisdiction with due diligence.

Sixtieth Defense

60. In accordance with General Obligations Law 15-108, if Plaintiff executes a release or a covenant not to sue for a tortfeasor in this action, Plaintiff's damage claim against Defendant is reduced to the extent of any amount stipulated by the release or covenant, or in the amount of consideration paid for it, or in the amount of the released tortfeasor's equitable share of the damages under CPLR 1401 et seq., whichever is greatest.

Sixty-first Defense

61. The conduct of Defendant and all activities with respect to the subject products were fair and truthful based upon the knowledge existing at the relevant time alleged in the Complaint. Therefore, Plaintiff's claims under New York Business Corporation Law § 349 are barred.

Sixty-second Defense

62. Plaintiff's claims are barred, in whole or in part, pursuant to South Carolina Code Ann. § 15-3-20.

Sixty-third Defense

63. Defendant reserves the right to supplement its assertion of defenses as it continues with its factual investigation of Plaintiff's claims.

IV.**PRAYER**

WHEREFORE, Defendant prays for judgment as follows:

1. That Plaintiff take nothing from Defendant by reason of the Complaint;
2. That the Complaint be dismissed;

- 1 3. That Defendant be awarded its costs for this lawsuit;
- 2 4. That the trier of fact determine what percentage of the combined fault or other liability
- 3 of all persons whose fault or other liability proximately caused Plaintiff's alleged injuries,
- 4 losses or damages is attributable to each person;
- 5 5. That any judgment for damages against Defendant in favor of Plaintiff be no greater
- 6 than an amount which equals their proportionate share, if any, of the total fault or other liability
- 7 which proximately caused Plaintiff's injuries and damages; and
- 8 6. That Defendant has such other and further relief as the Court deems appropriate.
- 9

10 December 20, 2007

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18 December 20, 2007

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25 Attorneys for Defendant
26 PFIZER INC.
27
28

JURY DEMAND

Defendant Pfizer Inc. hereby demands a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

December 20, 2007

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